

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-15 are pending in the application, with claims 1, 9, and 12 being the independent claims.

The title has been amended to delete the superfluous "New Prostate Cancer Antigen" recitation and to refer to "PCA3". The amendments to the claims have been done to clarify the invention, and support for such amendments can be found in the originally filed claims and throughout the specification.

Applicants thank the Examiner for the rejoining of all claims and inventions.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 102

Rejection Under 35 U.S.C. § 102(a)

The rejection of claims 1-7 and 11 under 35 U.S.C. § 102(a), as being anticipated by Verhaegh *et al.*, *J. Biol. Chem.* 275:37496-37503 (2000) ("Verhaegh") is respectfully traversed.

The three inventors on the instant application, Verhaegh, Bussemakers and Shalken, co-wrote the Verhaegh reference with two other co-workers. While it appears that these two co-workers are not inventors in the present application, the investigation regarding their contributions to the Verhaegh reference has not been completed. Since the results of this investigation may impact the manner in which Applicants respond to the outstanding 102(a) issues in this Application, Applicants will address these issues in

a supplemental response upon completion of the investigation. Applicants therefore request that this rejection be held in abeyance until the investigation can be completed.

Rejection Under 35 U.S.C. § 102(b)

The rejection of claims 1-6 under 35 U.S.C. § 102(b) as being anticipated by Bussemakers *et al.*, *Cancer Res.* 59:5975-5979 (1999) ("Bussemakers") is respectfully traversed.

The Examiner alleges that the genomic map of DD3 shown in Fig. 3 of Bussemakers, which does not show any sequence, "inherently contains the nucleic acids of instant claims 1 and 2." The Examiner further alleges that page 5976 of Bussemakers also anticipates vector claims 3 and 4, and that inherently, claims 5 and 6 are also anticipated. Applicants respectfully disagree.

Bussemakers does not teach or suggest the nucleic acid sequences recited in claims 1 or 2. These promoter sequences had not been characterized physically or by sequence prior to the present invention. Supporting this contention is Bussemakers at page 5979, left column, last sentence: "[l]ikewise, the DD3 gene promoter needs to be characterized."

Clearly, therefore, the promoter and regulatory sequences had not been identified and characterized in Bussemakers.

Further, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference. MPEP § 2112. In relying upon the theory of inherency, the Examiner must provide a basis to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teachings of the alleged prior art. MPEP § 2112.

The genomic map of DD3 set forth in Bussemakers does not necessarily disclose the sequences claimed in the present applicaiton. There is no indication, via extrinsic evidence or otherwise, that the sequences are disclosed. In fact, as discussed below, the extrinsic evidence indicates otherwise.

Bussemakers discloses two GeneBank accession numbers. Separate blasts of AF103908 and AF103907 (see p 5977, left column) failed to show any homology with the claimed sequences of the instant invention. Clearly Bussemakers does not anticipate, inherently or otherwise, the claimed invention because the sequences taught in Bussemakers are not claimed in the present invention.

Based on the foregoing, vector claims 3 and 4 and cell claims 5 and 6 are also not anticipated by Bussemakers. Withdrawal of this rejection is therefore respectfully requested.

Rejections under 35 U.S.C. § 103

The rejection of claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Verhaegh is respectfully traversed.

Applicants respectfully submit that in view of the investigation, mentioned above, regarding the contributions of the two co-authors of Verhaegh who are not inventors that the 103(a) rejection in view of Verhaegh be held in abeyance.

The rejection of claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Bussemakers is respectfully traversed.

As demonstrated above, Bussemakers does not teach or suggest the sequences of the present invention. Thus, Bussemakers, could not suggest a diagnostic method to assess promoter activity of the claimed promoter sequences.

In view of the above and foregoing it is respectfully submitted that the rejections of claims 1-7, 11 and 15 under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) be withdrawn.

Rejections under 35 U.S.C. § 112

The rejection of claim 8 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement is respectfully traversed.

While not acquiescing to the Examiner's rejection and in view of advancing the prosecution, claim 8 has been amended to recite antisense molecules. Applicants reserve the right to prosecute claims relating to other agents in further applications.

Applicants respectfully disagree with the Examiner's contention that the instant application does not provide guidance as to which antisense molecules inhibit transcription. It is respectfully submitted that a skilled artisan, cognizant of the sequence shown in Figure 1 and the promoter sequences taught at pages 6 and 7 and in Figure 7, could, without undue experimentation, design antisense molecules that would inhibit transcription of the PCA3 promoter.

The Examiner has further alleged that there is no correlation between the structure and function of antisense molecules when, in fact, such a correlation necessarily exists. Antisense molecules function to bind to a given nucleic acid molecule, and therefore the structure of that sequence can be hypothesized based only on its function, i.e., based on the sequence of the target molecule.

The Examiner is also referred to page 4, paragraph [0015] of the which teaches antisense molecules that hybridize to the -70 to -30 region of the promoter.

In view of the amendment to claim 8 and of the instant remarks, it is respectfully requested that the Examiner withdraw the rejection of claim 8 under 35 U.S.C. § 112, first paragraph.

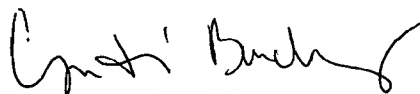
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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